

## **REMARKS**

### **Status of the Claims**

Claims 1-3, 5, 6, 9-13, 20 and 23-28 are pending in the present application, with claims 1 and 20 being independent claims. Claims 1, 5, 20, and 28 are amended. Claim 4 is canceled. Reconsideration of claims 1-3, 5, 6, 9-13, 20 and 23-28 is respectfully requested.

### **Amendments to the Claims**

Claims 1 and 20 are amended to include the recitation of former claim 4. Claim 4 is canceled without prejudice. Claims 5 and 28, formerly dependent from claim 4, are amended to depend from claim 1. Accordingly, the amendments do not add new matter.

### **Patentability**

Claims 1-3, 9, 20, 25 and 28 currently stand rejected under 35 U.S.C. §102(b) as being anticipated by Angel M.D. Papadopoulos, "Compound Implant to Project the Nasal Tip," Aesthetic Plastic Surgery 181-185 (1987) (herein "Papadopoulos"). Claims 4-6, 10-13, 23, 24, 26 and 27 currently stand rejected under 35 U.S.C. §103(a) as being unpatentable over Papadopoulos in view of U.S. Patent No. 6,773,458 to Brauker et al. (herein "Brauker"). Applicants disagree that the cited art renders the claims unpatentable. Nonetheless, the Applicants amend independent claims 1 and 20 to expedite prosecution of the claims, and claims depending therefrom. Such amendment, however, provides no indication whatsoever regarding Applicant's position of the patentability of former claims 1 and 20. Indeed, Applicant maintains the right to pursue former claims 1 and 20 in a related continuing application.

As amended, claim 1 is directed toward a biocompatible tissue implant comprising a naturally occurring biological tissue slice that includes an effective amount of viable cells that naturally occur within the tissue slice. The tissue slice is dimensioned so that the cells can migrate out of the tissue slice to proliferate and integrate with other tissue. *The tissue slice has a thickness of less than about 3 mm.* The implant also includes a retaining element for securing the tissue slice. As discussed in paragraphs [0033] and [0034], and further exemplified by the Examples 1, 2, and 3 in U.S. Patent Application Publication No. US 2005/012507, corresponding to the present application, tissue slices with the recited thickness can "ensure

proper migration of cells out of a tissue slice. As mentioned earlier, amended claim 1 includes the recitations to former claim 4.

Amended claim 1 is not anticipated or obvious in light of any combination of Papadopoulos and Brauker because neither reference teaches the recitations of the amended claim. As stated in the Final Office Action, Papadopoulos does not disclose a tissue slice with a thickness less than 3 mm (see Final Office Action dated November 8, 2006, page 3, first full paragraph). Indeed, Papadopoulos does not teach that its implant includes an effective amount of viable cells that can migrate out of the slice to proliferate and integrate with tissue at an injury or defect. Papadopoulos is directed to a nose-tip shaping implant. The use of the implant to migrate viable cells out of the implant is not suggested at all. Furthermore, Brauker fails to provide any disclosure or hint regarding naturally occurring tissue slices whatsoever; its implants are artificial constructs that are filled with cells. Accordingly, neither reference discloses the invention of amended claim 1, nor can the references be combined to disclose the elements of claim 1.

Though the Office Action asserts it would have been an obvious matter of design choice to modify the thickness of the implants in Papadopoulos, Applicants disagree because modification of the thickness would have rendered Papadopoulos inoperable for its intended purpose. Papadopoulos is directed to a nose implant for projecting a nasal tip in cosmetic surgery when a patient has thick skin, a depressed or slightly descending tip, and a minimal bony hump (see Papadopoulos, abstract). In particular, the reference discloses the use of septal cartilage as a “tent pole” to support implant (see *id.*, page 181, column 2), and the use of alar cartilages to shape the tip of the implant (see *id.*). Accordingly, one skilled in the art would not modify the cartilages of Papadopoulos to have a thickness less than about 3 mm because the cartilages would be too thin to support the nose shaping implant. The septal cartilage being less than 3 mm thick would not function as a “tent pole.” As well, an alar cartilage less than about 3 mm thick would not act as an appropriate structure for shaping the new nose tip of a patient with *thick skin*. Papadopoulos states that cuts need to be made in the alar cartilage tip so that they open like eagle wings to give shape to the tip (see *id.*). Accordingly, use of the thickness recitation of claim 1 would not allow the Papadopoulos implant to perform as discussed in the reference; such alteration would actually result in a structure that is too thin to perform the shaping intended,

rendering the structure inoperable. Accordingly, the thickness recitation of claim 1 is not a design choice of a skilled artisan to be applied to Papadopoulos.

As well, a skilled artisan would also lack motivation to alter the implant of Papadopoulos to practice an implant consistent with amended claim 1. The skilled artisan would only alter Papadopoulos in such a way as to properly give a desired shape to a patient's nose tip. There would be no motivation to alter the Papadopoulos implant to the dimensions recited in claim 1 since the implant would be structurally too fragile to properly shape the nose tip.

For at least all these reasons, the cited art cannot sustain a prima facie case of obviousness against claim 1. Accordingly, claim 1 is patentable.

Claims 2, 3, 5, 6, 9-13, and 28 all ultimately depend from claim 1. Accordingly, these claims are all patentable for at least the same reasons that claim 1 is patentable. The claims, however, are also patentable for other reasons. For examples, claims 5 and 6 are patentable because none of the cited art teach the thickness recitations of these claims. Indeed, Papadopoulos would be so much more inoperable if modified to practice claims 5 and 6 because of the relatively thin dimensions recited therein.

Claim 20 is amended to include a recitation "the tissue slice having a thickness less than about 3 mm." Accordingly, the claim is patentable for at least the same reasons that claim 1 is patentable.

Claims 23-27 depend ultimately from claim 20. Accordingly, each of the dependent claims is patentable for at least the same reasons that claim 20 is patentable.

**CONCLUSION**


In view of the remarks above, Applicant submits that claims 1-3, 5, 6, 9-13, 20 and 23-28 are in condition for allowance, and allowance thereof is respectfully requested. Applicant encourages the Examiner to telephone the undersigned in the event that such communication might expedite prosecution of this matter.

In the event that a petition for an extension of time is required to be submitted at this time, Applicant hereby petitions under 37 CFR 1.136(a) for an extension of time for as many months as are required to ensure that the above-identified application does not become abandoned.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 141449, under Order No. 22956-235.

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Respectfully submitted,

By:   
Charlton Shen  
Registration No. 54,442  
NUTTER MCCLENNEN & FISH LLP  
World Trade Center West  
155 Seaport Boulevard  
Boston, Massachusetts 02210-2604  
(617) 439-2000  
(617) 310-9000 (Fax)  
Attorney for Applicant